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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,022	08/18/2003	Michael J. Welsh	P04404US01	3206

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DES MOINES, IA 50309-2721

EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,022	WELSH ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on April 12, 2006, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's persuasive arguments.

It is acknowledged that Applicant has properly claimed priority to US 09557506

Maintained Rejections:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and new claims 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth previously. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to treating conditions by administering a therapeutically-effective amount of an antagonist, agonist, or modulator of DEG/ENaC channel proteins, however no such therapeutically effective compounds are known to exist and nor does the specification describe them. Waldmann-R et al., Ann NY Acad Sci, 30(67-76)1999 state that

protons are the only known activator (agonist) of DEG/ENaC channel proteins (ASIC channels), and indicate that activation of these channels contributes to disease states in ischemia and epileptic sezures (page 74); the specification has not taught which agonists would be useful for treating any particular disorder, and nor would agonists be expected to be useful as taught by Waldmann-R et al. Furthermore, Deagle-WR, US Patent Publication 2005/0267009, teach that amiloride is the only known compound that blocks ASICs, however the effect is not potent and not selective as indicated by amiloride's potent blockade of other receptor targets, which precludes its clinical use as an ASIC antagonist (see paragraph 0107).

While it is certainly reasonable to expect that specific antagonists of specific DEG/ENaC channel proteins would some day be found and prove useful in the treatment of disorders such as pain and inflammation, as discussed by Waldmann-R et al., at the bottom of page 74, the instant specification provides no teaching of these yet to be found useful compounds. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a methods of treatment using unknown compounds; thus the specific benefit set forth in the claims does not exist in a currently available form. "Tossing out the mere germ of an idea does not constitute enabling disclosure... [R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention."

Genentech, Inc. v. Novo Nordisk Inc., 108 F.3d 1361, 1366, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997).

Due to the large quantity of experimentation necessary to find compounds that can be used in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which indicates that such compounds are not known to exist, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and use the claimed invention.

Applicant argues that methods for identifying compounds which inhibit, activate or modulate the acid-sensing ion channels were known in the art as of Applicant's priority date as recognized by the examiner. This argument has been fully considered but not deemed persuasive. The issue is that the claims require such compounds. The methods referred to above only recognize a given compound as inhibiting, activating or modulating the acid-sensing ion channel; they do not produce such compounds.

Applicant argues that a patent need not teach and preferably omits what is well known in the art. This argument has been fully considered but not deemed persuasive. One skilled in the art, attempting to practice applicant's claimed invention, would assuredly want to be taught what compounds could be used to practice it. Instead, the instant specification simply invites that artisan to try to find such compounds, if they can indeed be found.

Applicant argues that just as the Hybritech court recognized that the methods for screening monoclonal antibodies was well known, the methods for screening for inhibiting,

activating or modulating the acid-sensing ion channel was well known in the art prior to the filing date of the instant application. This argument has been fully considered but not deemed persuasive. The production of specific monoclonal antibodies was and is well known; the production of compounds that can be used to practice the claimed invention is completely unknown.

New Rejection:

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims require compounds for treating conditions associated with the response of acid-sensing ion channels, yet known are taught in the specification and nor are any known in the art. Waldmann-R et al., Ann NY Acad Sci, 30(67-76)1999 state that protons are the only known activator (agonist) of DEG/ENaC channel proteins (ASIC channels), and indicate that activation of these channels contributes to disease states in ischemia and epileptic sezures (page 74); the specification has not taught which agonists would be useful for treating any particular disorder, and nor would agonists be expected to be useful as taught by Waldmann-R et al. Furthermore, Deagle-WR, US Patent Publication 2005/0267009, teach that amiloride is the only known compound that blocks ASICs, however the effect is not potent and not selective as indicated by amiloride's potent blockade of other receptor targets, which precludes its clinical use as an ASIC antagonist (see paragraph 0107)

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the required "composition that inhibits, activates or modulates the acid sensing ion channels...in a therapeutically-effective amount", and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

June 24, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER